

REMARKS

I. Amendments to the claims

Claims 1-13 are pending in this application. Claims 1, 3, and 8 have been amended to correct typographical mistakes. Claim 4 has been amended to a proper multiple dependent claim. Claim 8 and 9 have been amended to include proper antecedent basis for amine salt and to remove reference to preferable limitations. Claim 10 has been amended to insert the correct structure for formula II as described on page 3 of the specification, to add the definition of R₁ from claim 1, and to delete the proviso clause. New claims 11-13 have been added as a result of the amendments to claims 4, 8, and 9. No new matter has been added as a result of the amendments to the claims.

II. Response to the claim objections

Claim 4 was objected to as being an improper dependent claim. Applicant has amended claim 4 to depend on claim 1 or 2. Reconsideration and withdrawal of the claim objection is respectfully requested.

III. Response to the rejection under 35 U.S.C. § 112, second paragraph

Claims 1-3 and 5-10 were rejected as being indefinite. Applicant has amended claims 8 and 9 as explained above to remove any reference to preferable limitations. Further, claims 8 and 9 have been amended to insert proper antecedent basis for the amine salt.

With regards to the dotted line in the structure of claims 1 and 10, Applicant respectfully submits that the skilled artisan would know that a bond represented by ----- means a double or single bond. For example, ChemDraw Ultra (v11.0) defines ----- as either single or double bond. In fact, a person of ordinary skill in the pertinent art would know that structures with ----- bonds represent single or double bonds. This is the practice in the field. See cited references Chernyak and La Loggia. Thus, the claims are not indefinite.

Based on the above discussion, Applicant respectfully requests reconsideration and withdrawal of the rejection under the second paragraph of section 112.

IV. Response to the rejection under 35 U.S.C. § 102(b) and (e)

Claims 1-3, 5-8 and 10 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by La Loggia (U.S. Pat. No. 6,794,503). Claim 10 was rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by MacDonald (U.S. Pat. No. 4,255,331). Claims 1-3 and 5-

10 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Chernyak (WO2003/047329). Applicant respectfully submits that cited references do not anticipate the pending claims.

In order for a reference to anticipate the claims of an invention, that reference must teach each and every element set forth in the claims. MPEP. § 2131; *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996); *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). In other words, an anticipatory reference must disclose the identical invention in as complete detail as is contained in the claims. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

Applicant points out that independent claim 1 is directed to a process for the preparation of 6 α -fluoro compounds of formula I comprising the fluorination of pregnane derivatives in the 6-position with an electrophilic fluorination agent, in an inert solvent and at ambient temperatures, characterized in that (1) a compound of formula II is reacted with an electrophilic fluorination agent (2) in the presence of a salt of a strong acid with a nitrogenous base under (3) substantial water-free reaction conditions. Claims 2-9 depend from claim 1 and include all the limitations of claim 1. The process of claims 1-9 comprises fluorinating the formula II compound that have a R₁-C(O)-O-group at the 3-position wherein R₁ is a phenyl or a phenyl substituted with the groups recited in claim 1. Independent claim 10 is directed to the compounds of formula II.

Claims 1-9 are not anticipated by the cited references. La Loggia teaches a process that does not involve fluorinating a compound having a phenyl or a substituted phenyl at the 3-position, like formula II of the present claims. Similarly, the Chernyak and the MacDonald processes do not involve fluorinating a compound having a phenyl or a substituted phenyl at the 3-position. Accordingly, the cited references do not anticipate claims 1-9 because the references describe processes that are different than the process of claims 1-9.

Further, claim 10 is not anticipated by the cited references. La Loggia teaches compounds of formula (III) wherein R' in the 3-position is a carboxyalkyl group or acetoxy. La Loggia at col. 2, lines 43-65 and col. 4, lines 18-25. Chernyak teaches compounds of formula (II) wherein R⁴ in the 3-position is C(O)-R_d wherein R_d is alkyl, aryl or heteroaryl (such as a phenyl, naphthyl, quinolinyl, isoquininyl, or pyridyl). Chernyak at paragraphs [0011] and [0026]. MacDonald teaches certain compounds wherein the 3-position is substituted with acetoxy. MacDonald at col. 1, lines 62-63. None of the compounds in the cited references are compounds having a R₁-C(O)-O-

group wherein R₁ is a phenyl substituted with the groups recited in claim 10. Thus, claim 10 is not anticipated by the cited references.

Thus, Applicant respectfully requests reconsideration and withdrawal of the anticipation rejections.

V. Response to the Obviousness-Type Double Patenting

Claim 10 was rejected as obviousness-type double patenting over claims 1 and 6 of MacDonald. The Examiner asserted that although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the prior art patent anticipate the instant claim. Applicant respectfully submits that claim 10 is not obviousness-type double patenting because MacDonald does not anticipate claim 10. As pointed out above, claim 1 and 6 of MacDonald describe compounds wherein the 3-position is substituted with acetoxy, not an R₁-C(O)-O- group wherein R₁ is a substituted phenyl group. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the obviousness-type double patenting rejection.

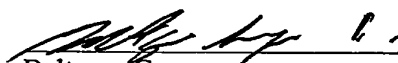
VI. Conclusion

Applicant believes that claims 1-13 are in condition for allowance, and a Notice of Allowance is respectfully requested. The Examiner is invited to contact the Applicant's undersigned representative at (215) 293-6477 if the Examiner believes that this would be helpful in expediting prosecution of this application.

Respectfully Submitted,

Dated: July 6, 2009

By:


Baltazar Gomez
Reg. No. 61,924
Teva Pharmaceuticals NA
425 Privet Road | Horsham, PA 19044
215.293.6477 phone | 215.293.6499 Fax
baltazar.gomez@tevausa.com
Customer Number 26646